

Application Number 10/687,336
Response to Final Office Action mailed January 14, 2008

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REMARKS

This submission is responsive to the Final Office Action dated January 14, 2008. Claims 50-58 are pending. In view of the following remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections set forth in the Final Office Action.

Claim Rejections Under 35 U.S.C. § 103(a)

In the Final Office Action, claims 50-55 and 58 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Schulman et al. (U.S. Patent No. 6,088,608, hereinafter "Schulman") in view of Brune (U.S. Patent No. 5,984,875), and further in view of Ishikawa et al. (U.S. Patent No. 6,398,710, hereinafter "Ishikawa") and Scarantino et al. (U.S. Patent No. 6,402,689, hereinafter "Scarantino"). The Final Office Action also rejected claims 56-57 under 35 U.S.C. § 103(a) as being unpatentable over Schulman in view of Brune, Ishikawa, and Scarantino, and further in view of Kumar et al. (U.S. Patent No. 6,416,471, hereinafter "Kumar") Applicant respectfully traverses these rejections. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions.

With reference to independent claim 50, for example, the applied references lack any teaching that would have suggested a system for measuring physiological parameters in the body of a patient indicative of gastroesophageal reflux. As recited in claim 50, the system includes a plurality of sensors adapted to be implanted in the body of a patient. Each of the plurality of sensors periodically measures a physiological parameter indicative of gastroesophageal reflux and periodically transmits a signal indicative of the physiological parameter that is indicative of gastroesophageal reflux. Each of the signals includes an identifier that is indicative of the sensor from which the signal is sent. The system further includes a receiver that receives the signals from the plurality of sensors, determines a location for each sensor within an esophagus based on the identifier, and monitors the physiological parameter indicative of gastroesophageal reflux as a function of distance based on the signals and the locations.

In support of the rejection of claim 50, the Final Office Action characterized Schulman as disclosing a system for measuring physiological parameters in the body of a patient. According to the Final Office Action, the system includes a plurality of sensors that periodically measure a

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physiological parameter indicative of gastroesophageal reflux such as pH and transmit a signal indicative of the physiological parameter that is indicative of gastroesophageal reflux, and a receiver that receives and record the signals. The Final Office Action correctly identified that Schulman does not disclose that each signal transmitted by the plurality of sensors includes an identifier that is indicative of the sensor from which the signal is sent, and cited Brune as teaching an analogous measuring system in which the sensors transmit a signal including an identifier code that is indicative of the sensor from which the signal is sent. The Final Office Action then stated it would have been obvious to include the identifier code taught by Brune in the signals of Schulman to differentiate the particular sensor from which each signal was sent.

The Final Office Action also correctly identified that Schulman in view of Brune does not disclose that the receiver determines a location for each sensor within an esophagus based on the identifier and monitors the physiological parameter indicative of gastroesophageal reflux as a function of distance based on the signals and location. The Final Office Action cited Ishikawa and Scarantino in an attempt to overcome these deficiencies of Schulman in view of Brune. The Final Office Action characterized Ishikawa as teaching that the location of a plurality of implanted sensors is determined based on an identifier to allow proper determination of a desired process based on the known location. Scarantino was characterized as teaching a plurality of implanted sensors positioned at different locations to gain more regional specific information regarding the site of placement, such as when measuring pH for gastrointestinal applications. The Final Office Action then stated that it would have been obvious to modify the system of Schulman in view of Brune with the teachings of Scarantino and Ishikawa to enhance the invention by taking into account the effect of location/distance of the sensor for the measurement of the physiological parameter indicative of gastroesophageal reflux and thus provide a more specific determination of such.

However, Applicant respectfully disagrees; the proposed combination would not have been obvious to one of ordinary skill in the art at the time of the invention.

Schulman is generally directed to an electronic sensor that periodically performs integrity tests to verify the proper operation of the sensor.¹ One integrity test may include comparing the

¹ Schulman, Abstract.

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output of multiple sensors located in the same general tissue area.² The sensors may be assumed to be working correctly if the measurement data agrees within a certain threshold value, such as, for example, 20%.³ If one of the sensors disagrees with the other sensors by more than, for example, 20%, the data from this sensor may be ignored, or the sensor may be disabled.⁴ The sensors may measure pH.⁵

Brune is generally directed to a system including a number of ingestible boluses for monitoring physiological parameters of individual animals in a group or herd.⁶ Each of the boluses transmits a unique identification code.⁷ The bolus may include a pH sensor.⁸

Ishikawa is generally directed to a system including one or more transponders for detecting radiation in a patient during tumor treatment and transmitting such data by radio frequency signals to an external processor.⁹ The transponder can be encoded with a unique identification code, and a position sensing system precisely locates each transponder using radio frequency transmission signals.¹⁰ This allows precise measurement of radiation dosing in specific areas of the tumor and surrounding tissue.¹¹ The processor apparently determines the location of each transponder through triangulation of the RF signal output by a transponder using two RF receivers and a CPU antenna.¹² Ishikawa mentions pH only once, in reference to the fact that a coating, such as phosphosilicate glass, may be applied to a transponder to enable the transponder to withstand very low pH levels.¹³

Scarantino is generally directed to a system for monitoring and evaluating the status of a tumor undergoing treatment.¹⁴ Scarantino describes that the system may monitor tumor or organ

² Schulman, Col. 5, ll. 58-63.

³ *Id.* at Col. 5, l. 66 to Col. 6, l. 3.

⁴ *Id.* at Col. 6, ll. 3-7.

⁵ *Id.* at Col. 4, l. 64.

⁶ Brune, Col. 3, ll. 1-5.

⁷ *Id.*

⁸ *Id.* at Col. 5, ll. 23-27.

⁹ Ishikawa, Col. 4, ll. 26-31.

¹⁰ *Id.* at Col. 4, ll. 35-39.

¹¹ *Id.* at Col. 4, ll. 40-42.

¹² *Id.* at Col. 5, ll. 17-31.

¹³ *Id.* at Col. 8, ll. 8-14.

¹⁴ Scarantino, Abstract.

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physiological and biological parameters,¹⁵ that a physiological parameter may include pH,¹⁶ and that the sensors may be used in a gastrointestinal tract.¹⁷

The Final Office Action relies on these four references to support the rejection of Applicant's claim 50. It is unclear how or why a person having ordinary skill in the art would have combined references directed to sensor integrity tests (Schulman), monitoring a group of animals (Brune), radiation dosimetry (Ishikawa) and evaluating tumor treatment (Scarantino) to reproduce the invention of Applicant's claim 50, as asserted by the Final Office Action. The combination of so many references with unrelated teachings would have only been made with the benefit of hindsight and Applicant's disclosure. In addition, there are numerous reasons why a skilled person would not have been motivated to combine the references to produce the invention of Applicant's claim 50.

For example, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.¹⁸ As described above, Schulman is directed to comparing the output of multiple sensors located in the same general tissue area to ensure proper operation of sensors. In the system including multiple implanted sensors, the output from each sensor is compared to the outputs of the other sensors to determine if each sensor is working correctly. As described in the Amendment dated September 27, 2007, if, for example, the substance does have a different value (e.g., greater than about 20% different) at the location of one of the sensors, this sensor will be assumed to be operating incorrectly, and its data will be ignored or the sensor will be disabled.

Different values can be expected, in at least some cases, when monitoring a physiological parameter indicative of gastroesophageal reflux as a function of distance, as required by claim 50. If the sensors of Schulman sensed these different values, the result would be at least one, and possibly more, of the sensors being disabled. Clearly, the system of Schulman would have provided no suggestion or motivation to a skilled person to produce the invention of claim 50. Moreover, it is clear that modifying Schulman to monitor the physiological parameter indicative

¹⁵ *Id.* at Col. 8, ll. 55-63.

¹⁶ Scarantino, Col. 8, ll. 55-63.

¹⁷ *Id.* at Col. 8, ll. 63-66.

¹⁸ MPEP 2143.01, citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

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of gastroesophageal reflux as a function of distance would render Schulman unsatisfactory for its intended purpose, which would further discourage a person having ordinary skill in the art from making the proposed modification.

As another example, none of the references discloses or suggests a receiver that determines a location for each sensor within an esophagus based on the identifier. First, Ishikawa is the only reference that discloses determining a location of a sensor, and these sensors are implanted in a tumor or in tissue surrounding the tumor. There is no suggestion that the sensors may be located within an esophagus and, therefore, no suggestion of determining a location within an esophagus.

Moreover, Ishikawa only uses the identification code to sequentially query the transponders. However, the location is determined based on triangulation using signals received at two RF receivers and a CPU antenna. This is in contrast to Applicant's requirement of determining a location for each sensor within an esophagus based on the identifier.

Additionally, none of the references teaches or suggests monitoring a physiological parameter indicative of gastroesophageal reflux as a function of distance based on the signals and locations within an esophagus. As described briefly above, Schulman, Brune and Scarantino do mention that pH may be monitored. However, none of the references discloses that measuring pH, or any other physiological parameter indicative of gastroesophageal reflux, as a function of distance is practicable or even desirable.

In summary, the references cited in the rejection of claim 50 cannot be combined without rendering the sensors of Schulman unsuitable for their intended purpose, the references provide no teaching or suggestion of a receiver that determines a location for each sensor within an esophagus based on the identifier, and none of the references teaches or suggests monitoring a physiological parameter indicative of gastroesophageal reflux as a function of distance based on the signals and locations within an esophagus. Kumar fails to provide any disclosure sufficient to overcome the deficiencies of Schulman, Brune, Ishikawa and Scarantino.

Claims 51-58 depend from claim 50 and are in condition for allowance for at least the reasons presented above with respect to claim 50. Additionally, the dependent claims introduce limitations that are neither disclosed nor suggested by the applied references.

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For example, claim 58 requires that the receiver monitors a change in pH as a function of distance from a lower esophageal sphincter. As described above, the applied references fail to disclose or suggest monitoring a physiological parameter that is indicative of gastroesophageal reflux as a function of distance. Certainly, then, the references do not teach or suggest a receiver that monitors a change in pH as a function of distance from a lower esophageal sphincter.

Furthermore, as described above, the intended purpose of the Schulman reference is to provide integrity checks for sensors. Monitoring a change in pH as a function of distance would render the sensors of Schulman unsuitable for their intended purpose. That is, Schulman disregards any data that differs from data collected by other sensors by more than a threshold percentage (e.g., 20%). This implicitly assumes that the data should be within a certain range of data from the other sensors. However, in Applicant's claim 58, a receiver monitors a change in pH as a function of distance. That is, the receiver monitors how pH varies over a distance and, accordingly, there may be different values measured by at least some of the plurality of sensors. Thus, using the sensors described in Schulman would not enable monitoring a change in pH as a function of distance, as any data that differs from data collected by other sensors by more than a threshold amount would be disregarded. Conversely, modifying the sensors of Schulman to enable monitoring a change in pH as a function of distance would render the sensors unsuitable for providing integrity checks for the sensors by comparing the output of multiple sensors. Thus, a person of ordinary skill in the art would have no motivation to modify Schulman to produce the invention of Applicant's claim 58 as proposed by the Final Office Action.

For at least these reasons, the Final Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 50-58 under 35 U.S.C. § 103(a). Withdrawal of this rejection is respectfully requested.

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CONCLUSION

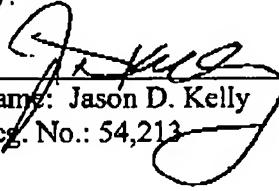
All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

3-14-08

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

By:


Name: Jason D. Kelly
Reg. No.: 54,213